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8 UNITED STATES DISTRICT COURT

9 DISTRICT OF ARIZONA

10 In Re Bard IVC Filters Products
11 Liability Litigation

No. MD-15-02641-PHX-DGC

**PLAINTIFFS' RESPONSE TO
DEFENDANTS C. R. BARD, INC.'S
AND BARD PERIPHERAL
VASCULAR, INC.'S MOTION TO
EXCLUDE THE OPINIONS OF
ROBERT O. RITCHIE, PH.D.**

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16 Plaintiffs oppose Defendants' Motion to Exclude the Opinions of Robert O.
17 Ritchie, Ph.D. ("Motion" or "Mot.") [Doc. 7316]. Plaintiffs incorporate in this response
18 their Omnibus Statement of Law and Generally-Applicable Arguments in opposition to
19 Bard's Motion to Exclude Plaintiffs' Experts and Rule 702 and *Daubert* ("Omnibus
20 Mem.") [Doc. 7799], filed contemporaneously herewith. For the reasons set forth below
21 and in the Omnibus Memorandum, this Court should deny the Motion.

22 **I. INTRODUCTION**

23 Dr. Ritchie is a mechanical engineer with special expertise in materials science.
24 He was retained by Plaintiffs to examine several Bard IVC filters that had failed in order
25 to provide an opinion as to why the failures occurred. He concluded that the filter devices
26 were defectively designed and manufactured and unsafe for implant in the human body.
27 Notably, Defendants do not challenge these opinions.
28

1 Instead, Defendants seek to exclude four opinions expressed by Dr. Ritchie that lie
 2 on the periphery of his proffered testimony. The four opinions collectively represent only
 3 a small fraction of the analysis Dr. Ritchie set forth in his reports and deposition
 4 testimony. None of the opinions targeted by Defendants relate to the core of his
 5 testimony: namely, that the Bard filters he examined failed for reasons that have been well
 6 documented in the literature regarding Bard's filters. Nonetheless, each of the opinions
 7 challenged by Defendants is based on a scientifically sound methodology and will assist
 8 the trier of fact. For this reason, Defendants' motion should be denied.

9 **II. ARGUMENT**

10 Consistent with Case Management Order No. 26 [Doc. 6799], and in the interest of
 11 judicial economy, Plaintiffs incorporate by reference Plaintiffs' Omnibus Statement of
 12 Law in Opposition to Bard's Motions to Exclude Plaintiffs' Experts Under Rule 702 and
 13 *Daubert* [Doc. 7799]. Plaintiffs rely specifically on sections I, II(B), and II(D) of their
 14 omnibus brief.

15 **A. Dr. Ritchie's background in mechanical engineering and materials** 16 **science qualifies him to opine on Bard's IVC filters.**

17 Dr. Ritchie is currently the H.T. & Jessie Chua Distinguished Professor of
 18 Engineering, Professor in the Department of Materials Science & Engineering, and
 19 Professor of Mechanical Engineering at the University of California, Berkeley. Mot. Ex.
 20 A, Ritchie March 2, 2017 Report, at 106. He is also Senior Faculty Scientist in the
 21 Materials Sciences Division of the Lawrence Berkeley National Laboratory, and an
 22 affiliated member of the UCSF/UC Berkeley Bioengineering group. *Id.* He was
 23 Chairman of the UC Berkeley Materials Science & Engineering Department from 2005 to
 24 2011. *Id.*

25 Dr. Ritchie received a Ph.D. in Materials Science in 1973 from Cambridge
 26 University. *Id.* His career in academia has taken him from Cambridge to M.I.T. to the
 27 University of California at Berkeley. *Id.* He has served as a consultant for both
 28 government and industry, including in the medical field on behalf of Abbott Vascular,

1 ATS Medical, Baxter, Cordis, Carbomedics, Edwards, Guidant, CV Medical, Medstone,
 2 NDC, Shiley, Sorin, and St. Jude Medical. *Id.* Dr. Ritchie is well known for his research
 3 in the fields of materials science, fracture mechanics and particularly fatigue, having
 4 authored or co-authored over 700 papers and authored or co-authored over 700 papers and
 5 edited 19 books in the technical literature (he is one of ISI's Highly Cited Authors in
 6 Materials Science). *Id.* During the course of his career Dr. Ritchie has received numerous
 7 awards, is a member of the National Academy of Engineering, and is a Fellow of the
 8 Materials Research Society, the American Society for Materials, and the American
 9 Society for Mechanical Engineers. *Id.* at 106-107.

10 Over the past forty-five years Dr. Ritchie has performed extensive research into the
 11 problem of fracture and fatigue of metallic alloys. Mot. Ex. C, Ritchie May 12, 2017,
 12 Rebuttal Report at 1. He has significant experience in the analysis of failures in medical
 13 devices specifically. *Id.* He has testified on numerous occasions before the Food and
 14 Drug Administration on issues pertaining to the fatigue, fracture and endurance of medical
 15 devices. *Id.* While Dr. Ritchie has not published on IVC filters, he has voluminous
 16 knowledge of the fatigue and failure of Nitinol (the alloy from which Bard filters are
 17 made) based on thirty years of active research on this material. *Id.*

18 **B. Dr. Ritchie is qualified to rely on published literature and the analysis**
 19 **of other experts to opine on failure rates.**

20 Bard maintains Dr. Ritchie is not qualified to opine on IVC failure rates because he
 21 is not a biostatistician or epidemiologist. This argument is a red herring – neither
 22 Plaintiffs nor Dr. Ritchie ever claimed that he was qualified to analyze raw adverse event
 23 data in order calculate failure rates. Rather, and as discussed *infra*, Dr. Ritchie relied on
 24 two distinct sources of information for his opinion regarding high failure rates: (1) the
 25 rates reported in the published literature; and (2) the relative risks that were calculated by
 26 Plaintiffs' expert Dr. Betensky, who is indisputably qualified to make these calculations.
 27 Thus, Dr. Ritchie did not attempt to calculate a failure rate, but instead relied on
 28

1 calculations performed by others and then opined on the significance of those calculated
2 rates. This was reasonable, and customary for experts.

3 Defendants never explain why a mechanical engineer with more than four decades of
4 experience researching and testing failures in medical devices is not qualified to render an
5 opinion on whether a given failure rate can be characterized as “high” or “unacceptable.”
6 Such opinions are part and parcel of the conclusions that any materials scientist would
7 render when evaluating the performance of a device.

8 In addition to questioning Dr. Ritchie’s qualifications, Defendants also argue that
9 Dr. Ritchie’s methodology was flawed because he couldn’t identify the rate of failure or
10 the sources he relied upon. Mot. at 6. This argument is particularly bewildering given
11 that, in the very same section that Defendants make this argument, they quote at length
12 from the portion of Dr. Ritchie’s deposition where *he identifies a reported failure rate as*
13 *well as a number of sources that he is relying on for his opinions*. In the testimony quoted
14 by Defendants, Dr. Ritchie testified that he reviewed one study that demonstrated a failure
15 rate of forty percent. Mot. Ex. A, Ritchie Dep. Tr., at 133:5-12. In this same section of
16 his testimony, Dr. Ritchie referenced at least two sources by name that he is relying on for
17 his opinions regarding failures rates: the Nicholson study and the expert report of
18 Dr. Betensky. *Id.* at 133:5-134:5.

19 These sources were also identified and discussed in Dr. Ritchie’s expert report, in
20 addition to many others. Mot. Ex. B, Ritchie March 2, 2017, Report, at 3-4. Thus, while
21 Dr. Ritchie did not recite line and verse from each of the studies he is relying on during
22 his deposition, his expert report clearly identifies the studies. *Id.* (citing reference
23 numbers 6-11). Many of these studies utilize the same terminology as Dr. Ritchie when
24 describing the observed failure rates. *See, e.g.,* Ex. A, Kalva et al., *Recovery’ vena cava*
25 *filter: Experience in 96 patients*, Cardiovasc. Intervent. Radiol. 2006, 29:559-64, at 563
26 (“We found a high incidence of asymmetric deployment of the filter legs, fractures of the
27 device, and asymptomatic caval penetration by the filter arms.”); Ex. B, Hull et al., *Bard*
28 *Recovery filter: Evaluation and management of vena cava limb perforation, fracture and*

1 migration, J. Vasc. Interv. Radiol. 2009, 20: 52-60, at 57 (“the Recovery filter is
2 associated with a high rate of IVC arm perforation and structural weakness”).

3 Dr. Ritchie’s opinions regarding the high rate of complications in Bard’s filters
4 simply echo what is already reported in the literature. For this reason, his opinions should
5 not be excluded because they bear the hallmark of a scientifically reliable methodology.
6 *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999) (key indicia of reliability
7 is whether the expert’s methods are employed outside the courtroom).

8 In addition to the peer-reviewed literature, Dr. Ritchie also relied on the analysis of
9 Dr. Betensky for his opinions that the extent of complications in Bard filters is
10 unacceptable. Dr. Betensky is a biostatistician who was retained by Plaintiffs to conduct a
11 statistical analysis of adverse event reports for Bard’s retrievable filters as compared to
12 the 1995 Simon Nitinol Filter (“SNF”). Dr. Ritchie utilized the reporting risk ratios that
13 Dr. Betensky calculated in order to assess the comparative performance of Bard IVC
14 filters. Although Defendants suggest that such reliance is improper, courts routinely
15 admit testimony of experts who rely on other experts with regard to matters outside their
16 field of expertise. *See, e.g., Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1321 (Fed. Cir.
17 2014), *overruled on other grounds by Williamson v. Citrix Online, LLC*, 792 F.3d 1339,
18 1349 (Fed. Cir. 2015) (en banc) (“Experts routinely rely upon other experts hired by the
19 party they represent for expertise outside of their field”); *Dura Automotive Sys. of Ind.,*
20 *Inc. v. CTS Corp.*, 285 F.3d 609, 609; 13 (7th Cir. 2002) (“[I]t is common in technical
21 fields for an expert to base an opinion in part on what a different expert believes on the
22 basis of expert knowledge not possessed by the first expert.”); *Calva-Cerqueira v. United*
23 *States*, 281 F.Supp.2d 279, 300 (D.D.C. 2003) (“an expert economist may rely on the
24 opinions of other experts”). So long as this Court determines that Dr. Betensky’s opinions
25 satisfy the requirements of *Daubert*, there is no reason Dr. Ritchie may not rely on them.

26 In the end, Defendants are left to assert that an expert who specializes in materials
27 science should be forbidden from observing that failure rates as high as 40% are
28 unacceptable. Yet not even Bard would dispute that a 40 percent failure rate in an

1 implanted medical device is unacceptably high, and therefore Dr. Ritchie's testimony
2 should not be excluded.

3 **C. Dr. Ritchie's description of the "vicious circle" is based on a reliable**
4 **methodology.**

5 Defendants next target Dr. Ritchie's opinion that one complication can increase
6 the risk of other complications, leading to a "vicious circle" of multiple complications.
7 Defendants' suggest this opinion is mere conjecture and is not based on any data.
8 However, Bard's own witnesses have already agreed with Dr. Ritchie that filter
9 complications can work synergistically, such that the presence of one complication (e.g.
10 tilting) can increase the risk of other complications (e.g. migration). Moreover, there is
11 data from both Dr. McMeeking and published literature to support Dr. Ritchie's opinions
12 regarding the interconnected nature of filter complications.

13 Dr. Ritchie succinctly explained his reference to a vicious cycle during his
14 deposition:

15 Q. Now let's talk about tilt as it relates to perforation for a moment. What do
16 you rely on to opine that tilt can lead to perforation?

17 A. Well, again, it's—there's a series—McMeeking has done calculations on
18 this and has certain theories, but my feeling on this has been that – that
19 there's a linkage with some—with migration as well. Some degree of tilt
20 means that you have an anchor that's not anchored, and that means that the
21 ability of the filter to move is obviously elevated because you're not fully
22 anchored. Once the filter starts to move, the probability of perforation is
23 likely, and all these things relate to the possibility of fracture and—'cause
24 that's what we talked about earlier with the crack growing in different
25 directions. So I've—I've always seen this as what I call a vicious circle. It's
26 a synergy of events.

27 Ex. C, Ritchie Dep. Tr., at 123:5-21. The potential for a synergistic relationship among
28 different types of complications lies at the heart of Dr. Ritchie's concept of a vicious
circle. In Dr. Ritchie's report, he provides an illustration of this phenomenon whereby a
fracture of one leg leads to tilting which then results in migration and could ultimately lead
to perforation. Mot. Ex. B at 36.

1 A former Bard vice-president confirms that Bard was well aware of the synergism
 2 among different types of complications. Christopher A. Ganser was the head of quality
 3 assurance at Bard during the period from 2003 to 2007. Ex. D, Ganser Dep. T., at 14:12-
 4 15:14. He testified that he knew that tilting could increase the risk of other complications:

5 Q. When you were involved with -- I'm going to talk about the
 6 recovery in the G2 filter right now. You knew that there were
 7 issues with both of those devices not staying perfectly centered in
 8 the vena cava, true?

9 A. I knew there were reports of complaints where there was tilting.

10 Q. And that tilting was a condition that could put a patient at an
 11 increased risk of perforations, of migrations, of fracture and of
 12 the device not working for its intended purpose of stopping
 13 pulmonary embolisms. Did you know that?

14 A. The tilting could contribute to that.

15 *Id.* at 71:5-18.

16 The published literature also supports Dr. Ritchie's opinions, at least with respect
 17 to the relationship between tiling and migration. In a study published in 2009, the authors
 18 determined there was a statistically significant relationship between a tilt of more than 15
 19 degrees and subsequent migration. Ex. E, Binkert et al., *Technical Success and Safety of*
 20 *Retrieval of the G2 Filter in a Prospective, Multicenter Study*, Journal of vascular and
 21 interventional radiology, 20 (2009), 1449-53, at 1452. Thus, Dr. Ritchie's description of a
 22 vicious circle is consistent with actual data and is not, as Defendants suggest, some
 23 untested hypothesis.

24 Finally, the expert report of Dr. McMeeking repeatedly echoes Dr. Ritchie's
 25 assessment regarding the synergistic relationship between filter complications. For
 26 example, Dr. McMeeking writes:

27 In addition, fracture, through removing legs or arms or both, will
 28 make the remaining body of the filter more prone to tilt as it will be
 asymmetric, and the loss of legs, and arms in some cases, will make
 migration of the remaining body of the filter more probable as it will
 be less firmly attached to the vena cava wall. It is also possible that
 the asymmetry of the remaining filter body after fracture will lead to
 force distributions on the wall of the vena cava that will accelerate
 the rate at which one or more of the limbs penetrates and perforates

1 the vena cava wall. This point applies to all filters considered in this
2 report.

3 Ex. A to Defendants' Motion to Exclude of Robert M. McMeeking [Doc. 7314],
4 McMeeking March 3, 2017 Report, at 25; *see also id.* at 10 ("I have found that perforation
5 contributes to tilting, and tilting contributes to perforation."), 12 (noting that tilt increases
6 probability of fracture as a result of "alternating strains [that] are increased because of the
7 larger span between the points where the filter limbs engage the wall of the vena cava").

8 Although Dr. McMeeking shares Dr. Ritchie's assessment regarding the
9 interrelationship among different complications, Defendants did not seek to exclude
10 Dr. McMeeking's opinion on this issue. Their decision undermines Defendants' assertion
11 that Dr. Ritchie's opinions regarding the "vicious circle" should be struck under *Daubert*.

12 **D. Dr. Ritchie's decades-long experience with failure analysis renders him**
13 **qualified to opine on Bard's testing.**

14 Despite acknowledging the depth of Dr. Ritchie's experience in the field of
15 materials science and failure analysis, Defendants suggest that Dr. Ritchie is unqualified
16 to render opinions regarding the adequacy of Bard's testing. In leveling this critique,
17 Defendants misstate the substance of Dr. Ritchie's opinions. Dr. Ritchie did not simply
18 state that Bard's testing was inadequate because "some patients have experienced
19 complications with Bard's filters." Mot. at 12. Rather, Dr. Ritchie concluded that Bard's
20 testing was flawed because it failed to reveal the fractures and complications that
21 ultimately manifested time and time again in actual patients. Ex. C, Ritchie Dep. Tr., at
22 158:7-18. In this respect, Dr. Ritchie's opinion is entirely noncontroversial: it is self-
23 evident that *any* testing of a product should be designed to detect complications that occur
24 during real world use. If a testing program fails to discover a flaw that leads to an
25 unacceptably high failure rate in actual patients, then that program was inadequate.

26 The fact that Dr. Ritchie did not explain in precise detail how Bard's testing
27 protocol should have been improved is not relevant to *whether* the testing was inadequate.
28 Dr. Ritchie never suggested that improvements were not possible. On the contrary, he

1 identified specific steps that Bard could have been taken to improve its testing, including
 2 (1) increasing the severity of the loading conditions, (2) increasing the duration of the
 3 tests; (3) increasing the number of filters that were tested, and (4) testing multiple filter
 4 sizes. Mot. Ex. B, Ritchie March 2, 2017, Report, at 28, 31.

5 Other than noting their disagreement with Dr. Ritchie's opinions, Defendants never
 6 articulate why they find Dr. Ritchie's qualifications lacking. Nor could they. Dr. Ritchie
 7 has been studying fatigue problems for 49 years, and has fatigue tested "virtually every
 8 material on the planet." Mot. Ex. A, at 36:14-16. His testing experience includes setting
 9 up protocols and working with various testing machines in the laboratory environment.
 10 *Id.* at 37:7-18. He is "absolutely" qualified to address the adequacy of Bard's testing. *Id.*
 11 at 37:16-18.

12 **E. Dr. Ritchie should be permitted to testify that SNF is a safer alternative**
 13 **product.**

14 Defendants' final salvo is directed at Dr. Ritchie's opinion that the Simon Nitinol
 15 Filter is a safer alternative to the Recovery, G2 and similar filters. As was the case with
 16 Dr. Ritchie's opinion regarding high failure rates, his opinion regarding SNF is based on
 17 the statistical analysis performed by Dr. Betensky of SNF's adverse events relative to
 18 other Bard filters as well as studies in the published literature regarding comparative filter
 19 complication rates. Mot. Ex. A, Ritchie Dep. Tr., at 134:10-136:6, 140:6-141:10; Mot. Ex
 20 B, Ritchie March 2, 2017, Report, at 4.

21 The main thrust of Defendants' argument is that Dr. Ritchie may not rely on a
 22 permanent filter (SNF) to establish a "safer alternative" to Bard's retrievable filters
 23 because these filters are not functional equivalents. But this is a false dichotomy. As
 24 Dr. Ritchie noted at his deposition, all of Bard's so-called retrievable filters were in fact
 25 developed as permanent filters. Ex. C, Ritchie Dep. Tr., at 154:20-155:6. Thus, the
 26 functional equivalence of SNF and retrievable Bard filters is a basis to include rather than
 27 exclude SNF as a safer alternative product.
 28

1 Defendants' "functional equivalence" criticism was also leveled almost verbatim
2 against Plaintiffs' expert Dr. McMeeking in connection with Defendants' motion to
3 exclude Dr. McMeeking. Rather than simply rehash Plaintiffs' response a second time,
4 and consistent with Section I of Case Management Order No. 26, Plaintiffs incorporate by
5 reference section III(D) of their Memorandum of Law and Arguments in Opposition to
6 Defendants' Motion to Exclude the Opinions of Dr. McMeeking [Doc. 7806]. As these
7 arguments demonstrate, Bard's suggestion of significant and dispositive functional
8 differences between SNF and retrievable filters is contrary to Bard's own representations
9 and actions, the testimony of its own medical expert, and the evidence in this litigation.

10 Bard also objects to Dr. Ritchie's testimony on the ground that he is not a medical
11 doctor and is therefore not qualified to render an opinion on safer alternatives for a given
12 patient. But this misconstrues the nature of Dr. Ritchie's opinion, which is offered from
13 an engineering and materials science perspective rather than as a medical judgment.
14 Dr. Ritchie will not testify that for any particular patient a certain filter should have been
15 used. Instead, he is observing that, as an engineer who specializes in failure analysis, the
16 significant reduction in adverse event rates for SNF, combined with the known design and
17 manufacturing defects in Bard's retrievable filters, render SNF a safer alternative as
18 compared to other available filters manufactured by Bard. This testimony is certainly
19 helpful to the jury even though it is not directly applicable to the ultimate issue for a
20 particular plaintiff, because the jury should be apprised that alternative, safer *options* were
21 available and could have been considered.

22 **III. CONCLUSION**

23 Based on the foregoing reasons, Plaintiffs respectfully request that the Court deny
24 Defendants' motion to exclude Dr. Ritchie.

1 RESPECTFULLY SUBMITTED this 27th day of September, 2017.

2 GALLAGHER & KENNEDY, P.A.

3 By: /s/ Mark S. O'Connor

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13 **CERTIFICATE OF SERVICE**

14 I hereby certify that on this 27th day of September, 2017, I electronically
15 transmitted the attached document to the Clerk's Office using the CM/ECF System for
16 filing and transmittal of a Notice of Electronic Filing.

17 /s/ Gay Mennuti